BLOODBORNE PATHOGEN
EXPOSURE CONTROL PLAN

National Cancer Institute
Frederick Cancer Research and Development Center

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Introduction

The NCI-Frederick is committed to the safety and health of its employees. In keeping with this philosophy, a comprehensive employee safety program has been established, an integral portion of which is this Bloodborne Pathogen Exposure Control Plan.

PART I:

A. Purpose

The Bloodborne Pathogen Exposure Control Plan describes the policies, which have been adopted by this institution regarding the prevention of the transmission of the Human Immunodeficiency Virus (HIV), the Hepatitis B Virus (HBV) and other bloodborne pathogens in the workplace. These policies, based on guidelines established by the Occupational Safety and Health Administration (OSHA) and the Maryland OSHA Code of Maryland Regulations (COMAR), are designed to eliminate employee occupational exposure to infectious agents.

B. Scope

The Bloodborne Pathogen Exposure Control Plan encompasses all personnel who have occupational exposure to HIV, HBV and other bloodborne infectious diseases. The plan complements the Institutional Biosafety Committee (IBC) registration programs for human pathogens, human blood and body fluids, and recombinant DNA.

C. Applicability

This plan applies to all personnel at the NCI-Frederick who work with HIV, HBV, human blood, and other potentially infectious material. Additionally SAIC-Frederick employees located at offsite facilities that have an occupational exposure to blood-borne pathogens are also covered by this plan.

D. Responsibility for Policy

Safety and Environmental Protection Program (SEPP) and Occupational Health Services (OHS) will be responsible for maintaining, approving, and incorporating revisions to this policy. All proposed revisions must be submitted to SEPP for review. SEPP and OHS will review and update the plan annually.

E. Definitions

1. "Blood": human blood, human blood components, and products made from human blood.

2. "Bloodborne pathogens": microorganisms that are present in human blood and can cause disease in humans who are exposed to blood containing the pathogen. Of particular relevance are the HBV and the HIV.

3. "Contaminated": the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

4. "Contaminated sharps": mean objects that can penetrate the skin (needles, scalpels, broken glass, broken capillary tubes, etc.) and have or may have blood or other potentially infectious material on their surfaces.

5. "Decontamination": the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface to the point where they are no longer capable of transmitting infection and the surface is rendered safe for handling, use, or disposal.

6. "Engineering controls": equipment or other items (e.g., sharps disposal containers, hoods) that isolate the bloodborne pathogen's hazard in the workplace.

7. "Exposure incident": a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious material that results from the performance of an employee's duties.

8. "Occupational exposure": reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

9. "Other potentially infectious materials":

   (1) Human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, or any body fluid that is suspect or visibly contaminated with blood, all body fluids in situations where it is difficult or impossible to differentiate between body fluids; and

   (2) Any unfixed tissue or organ from a human living or dead; and

   (3) Any cell or tissue culture or organ culture that contains HIV, HBV or any other bloodborne pathogen; and

(4) Culture medium or other solutions containing HIV, HBV or any other bloodborne pathogen; and

(5) Blood, organs or tissues from experimental animals infected with HIV, HBV or any other bloodborne pathogen.

(6) Established human cell lines unless characterized to be free of bloodborne pathogens. Documentation of such verification is the responsibility of the primary investigator and must be provided to the Biological and Laboratory Safety Office, SEPP.

10. Parenteral": piercing mucous membrane or skin through events such as a needlestick, human bite, cut, or abrasion.

11. "Personal protective equipment": specialized clothing or devices worn by an employee for protection against a hazard.

12. "Production facility": an area established to provide industrial-scale, large-volume or high concentration production of HIV or HBV.

13. "Regulated waste": liquid or semi-liquid blood; other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; pathological and microbiological wastes containing blood or other potentially infectious materials.

14. "Research laboratory": any area producing or using large amounts of HIV or HBV but not in the volume found in production facilities.

15. "Source individual": any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients, individuals who donate or sell blood or blood components, clients of drug and alcohol treatment facilities and clients in institutions for the developmentally disabled. Source materials may include cell lines, repository cell lines, and unfixed tissues or organs.

16. "Special medical waste": blood and blood products, sharps, pathological or microbiological specimens, or other research samples perceived to contain contaminated laboratory materials.

17. "Sterilize": the use of a physical or chemical procedure to destroy all microbial life.

18. "Universal Precautions": an approach to infection control whereby all human blood and other potentially infectious materials are treated as if known to be infected with HIV, HBV, and other bloodborne pathogens.

19. "Work practice controls": methods that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., no recapping of needles).

PART II:

A. Policy

Exposure to infectious agents represents a potential health hazard. It is the policy of the NCI-Frederick that employees are entitled to information regarding the potential health hazards of any material used in their laboratories. This policy statement establishes a formal program to provide health and safety information and training in the proper handling of infectious agents in accordance with 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens. A copy of the OSHA standard can be obtained at the offices of SEPP in Building 426 in accordance with the "Communications of Hazards to Employees" guideline, 29 CFR 1910.1030 (g) 2(vii). A copy of the OSHA Bloodborne Pathogen Standard can also be found at the OSHA website www.OSHA.gov.

B. Responsibilities

1. Senior management is responsible for ensuring the implementation of the Bloodborne Pathogen Exposure Control Plan. All employees, including contractor and government employees, who meet the criteria in the OSHA standard are included in its provisions.

2. The Manager, Safety and Environmental Protection Program is responsible for general administration of this program. The Manager, Occupational Health Services is responsible for vaccination (i.e. Hepatitis B) and medical surveillance programs, including post-exposure medical evaluation and follow-up.

3. The Biological Safety Officer, who serves as the Institutional Biosafety Committee Secretary, is responsible for the registration of work involving pathogens, human blood and other potentially infectious material, recombinant DNA, or transgenic animals and the implementation of this Bloodborne Pathogen Exposure Control Plan.

4. SEPP is responsible for:

   a. assisting the investigator in the design of the laboratory and the selection of laboratory practices and engineering controls that ensure a safe working environment;

   b. providing technical guidance to any person responsible for matters pertaining to laboratory safety;

   c. inspecting laboratories to assess compliance with policies for the safe conduct of work involving infectious agents;

d. investigating all reported accidents which result in the exposure of personnel or the environment to infectious agents and recommending corrective action to prevent recurrence;

e. supervising decontamination procedures where accidents have resulted in contamination of laboratory areas;

f. developing information and conducting training programs to educate and implement methods for the safe handling of infectious agents;

g. In conjunction with OHS, ensuring that medical monitoring programs are adopted;

h. maintaining a file of reference materials available to employees on the hazards, safe handling, storage, and disposal of infectious agents;

I. determining when employee exposure monitoring may be required, and conducting such monitoring as needed.

5. OHS is responsible for.

a. Coordinating with SEPP and individual supervisors to determine eligibility of individuals and job descriptions for medical monitoring programs.

b. Coordinating and reviewing all new Hepatitis B and HIV Surveillance enrollment applications with SEPP.

c. Conducting baseline, periodic, and termination medical monitoring as indicated.

d. Maintaining records of medical interventions and exposure incidents as directed by 29 CFR 1910.1030.

e. When appropriate, conducting comprehensive vaccination programs for identified biological hazards.

f. In conjunction with SEPP, training affected individuals and groups on specific medical monitoring programs.

g. In the event of an exposure, conducting a confidential post-exposure medical evaluation and follow-up.

6. The Manager, Facilities Maintenance and Engineering (FME), is responsible for overseeing a program of routine testing, certification and maintenance for certain equipment including:

   a. biological safety cabinets upon installation, when relocated and at least annually thereafter;

   b. emergency showers that are to be tested semi-annually.

7. Laboratory and department supervisors are responsible for:

   a. acquiring the knowledge and information needed to recognize and control infectious agents in the laboratory;

   b. registering all work with human pathogens, human blood or other potentially infectious materials and recombinant DNA. A list of all registered laboratories is maintained by SEPP to identify areas where biohazards may exist. The responsible investigator completes the registration form, identifies the agent(s), the laboratory procedures, the employees working in the laboratory, and the specific safety policies used and enforced. Program registration is approved for three years. Updates shall be submitted to SEPP whenever changes in personnel, practices, facilities or equipment are made. Registrations will be renewed every three years upon submission of a completed current registration form.

   c. In conjunction with SEPP, selecting and employing laboratory practices and engineering controls that prevent or limit occupational exposure to infectious agents;

   d. informing those supervised employees listed on the principal investigator's registration forms, of the potential hazards associated with the use of infectious agents used in the laboratory.

   e. instructing employees in safe laboratory practices and the use of protective equipment, and in the procedures for dealing with accidents involving infectious agents;

   f. supervising, implementing and enforcing the safety performance of the staff to ensure that the necessary and safe laboratory practices and equipment are used;

   g. arranging for immediate medical attention by OHS and reporting to SEPP any accident that results in a spill or exposure incident;

h. provide OHS and SEPP with the following information: a description of the exposed employee's duties as they relate to the exposure incident, documentation of the route(s) of exposure and circumstances under which the exposure occurred, and results of the source individual or material's pathogenicity testing, if available;

I. assisting representatives of SEPP in investigating accidents;

j. investigating and reporting to SEPP any problems pertaining to the operation and implementation of laboratory practices or equipment;

k. ensuring the proper labeling of agents when they are removed from their primary containers;

l. ensuring that eyewash stations located in their area are tested routinely;

m. notifying OHS of persons who are working with human pathogens, human blood or other potentially infectious material;

n. informing emergency response personnel of potential hazards within a laboratory in the event of an accident, fire or any emergency situation;

o. properly indicating on job requisition what infectious agents the employer could be exposed to and the Biosafety level of the laboratory.

8. Employees are responsible for:

a. Understanding and complying with safety guidelines, regulations, and procedures required for the task assigned;

b. reporting unsafe conditions to the principal investigator, immediate supervisor, or SEPP;

c. reporting to the principal investigator or immediate supervisor all facts pertaining to any accident resulting in exposure of personnel or the environment to biological agents;

d. following first aid procedures in the event of an exposure incident;

e. routinely testing eyewash stations located in their area;

f. reviewing and signing the program's SOPs to document that she or he understands and will follow recommended safety practices.

C. Additional Procedures

1. Eligibility for Medical Programs

Eligibility for appropriate medical surveillance programs and immunizations will be determined by OHS according to occupational exposure. See Attachment #1, *Hepatitis B and HIV Surveillance Eligibility and Addition to Pathogen Registration*, if you have employees that are eligible for registration in a medical surveillance program.

a. Employees that have occupational exposure to blood or other potentially infectious materials are included in this program. These employees may include those in the following categories:

Animal Care	Protective Services
Laboratory Research	Occupational Health
Clinical Research	Repository
Clinicians	Safety
Production Technician	Student Intern
Service Worker	

b. Individuals with a job category that is not included in the above list of potential occupationally exposed employees, but do perform tasks which may result in an occupational exposure, will be identified by their individual unit supervisor/director. Each department will document the specific tasks that cause these employees to have an occupational exposure to bloodborne pathogens. These employees will be covered by this exposure control plan and must participate in training and other aspects of the exposure control plan.

c. The following are procedures in which occupational exposure may occur:

1. direct work with bloodborne pathogens such as HIV or HBV

2. direct work with blood or other potentially infectious material

3. inoculation of research animals with live HIV, HBV, or any bloodborne pathogen

4. necropsy of animals experimentally infected with HIV, HBV, or any

human bloodborne pathogen

5. administration of first-aid during emergency responses to accidents or injuries

6. direct patient care.

7. direct handling of special medical waste.

2. Methods of Compliance

a. Universal Precautions will be followed by all personnel. All body fluids, as defined by this plan, will be considered potentially infectious materials.

b. Engineering Controls - The facilities and equipment at the NCI-Frederick are designed and selected in accordance with the NCI-Frederick Health, Safety and Environmental Compliance Program Manual, the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories, current edition and the NIH Recombinant DNA Guidelines, current edition. Biological safety cabinets serve as primary barriers and are required for all work with known or suspected infectious materials. The selection of primary and secondary barriers is based on the pathogenicity of the agent, planned laboratory manipulations, and the potential for aerosolization.

Whenever possible and practicable new safety technology, such as shielded needles, self-sheathing needles, retracting needles or needleless systems, will be utilized.

Puncture resistant, labeled or color-coded, leakproof sharps containers, available from the warehouse, must be used for the safe disposal of needles and other sharps. No recapping, bending, breaking, or further manipulation of needles is permitted.

i. Needles and other sharps must not be jammed into the containers in such a way as to overfill the containers. Fill only to the indicated line on the container or until the container is 3/4ths full, whichever is less (Ft. Detrick Regulation 385-4, Management of Medical Waste, August 1, 1996).

ii. All sharps containers must be securely closed before removal or disposal. Sealed sharps containers shall be clearly labeled and discarded as medical waste.

iii. If outside contamination of the primary container occurs, or if the

specimen could puncture the primary container, then the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of the OSHA Bloodborne Pathogen standard.

SEPP reviews purchase requests for certain laboratory engineering controls such as biological safety cabinets and chemical fume hoods. Monitoring of facility design and the certification of engineering controls is performed by FME in conjunction with SEPP via site visits, inspections, and preventive maintenance.

Laboratory renovations and construction plans are reviewed by SEPP to ensure appropriate design, placement of biological safety cabinets, containment, traffic patterns, etc.

c. Work Practice Controls - Emphasis is placed on safe laboratory practices and techniques to minimize the risk of exposure to pathogens in the workplace. Safetygrams and the NCI-Frederick Health, Safety and Environmental Program Manual detail safe laboratory practices.

i. Handwashing facilities must be provided in all laboratories. Washing is an effective means of physical removal and dilution of infectious agents. Immediately after an exposure incident to skin or mucous membranes has occurred, employees must wash affected area with soap and water and/or flush mucous membranes with copious amounts of water.

Employees must wash their hands immediately after removal of gloves or other personal protective equipment.

ii. The use of scalpels and glass pipettes in laboratories is strongly discouraged. Plastic tubes and pipettes or safe sharps such as knives with retractable blades are recommended.

iii. **PIPETTING BY MOUTH IS NOT PERMITTED. ***

* Mouth pipetting is not permitted except for work involving certain embryologic procedures using special apparatus with two in-line filters and after special permission is granted by the Biological Safety Officer.

iv. Eating, drinking, smoking, applying cosmetics, handling contact lenses, or wearing contact lenses without goggles, safety glasses, or face shields is prohibited in laboratory work areas.

v. Food and drink must not be stored in laboratory refrigerators, freezers, shelves, cabinets or on countertops/benchtops.

vi. All procedures involving blood or other potentially infectious materials shall be performed in a biological safety cabinet if there is potential for splashing, spraying, spattering, or generation of droplets or infectious aerosols.

vii. Specimens of blood or other potentially infectious materials shall be placed in containers that prevent leakage during collection, handling, processing, storage, transportation, or shipping. Relevant state and federal regulations will be followed.

viii. Equipment will be decontaminated and tagged in accordance with NCI-Frederick internal SOP "Equipment Decontamination and Safety Clearance" before repair or service by FME or an outside contractor.

Safety Devices - OHS will be chairing a committee whose goal is to eliminate or reduce exposure to bloodborne pathogens. This committee will meet at least annually to review the use of medical devices designed to reduce needlestick injuries. Consideration and use of appropriate, commercially available, and effective safer devices will be documented. The committee will describe the devices identified for employee use, the method(s) used to evaluate those devices, and justification for the selection of the appropriate safety device. This committee also will solicit input from employees performing procedures using needle safe devices regarding the identification, evaluation, and selection of effective engineering controls, including safe medical devices.

3. Personal Protective Equipment (PPE):

Appropriate PPE is provided for employee use where there is occupational exposure. PPE will be considered appropriate only if it does not permit any potentially infectious material to pass through onto clothing, skin, eyes, mouth, or other mucous membranes. Minimal PPE to be worn is determined by the organisms and chemicals that are used, methods of use, and the biological containment level. Additional PPE may be required by the specific SOPs of the program.

The employer shall insure that appropriate PPE is in the appropriate sizes and is readily accessible at no charge to the employee.

Gloves, labcoats, face shields or masks, mouthpieces, resuscitation bags, or

other ventilation devices, protective suits, scrubs, and safety eyewear are provided at no cost to the employee. Individuals entering laboratories must comply with the established requirements for the area.

If a garment has been penetrated by blood or other potentially infectious material, the garment shall be removed immediately. All PPE must be removed before leaving the work area.

a. Gloves must be worn when the employee might have skin contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, or when handling contaminated items or surfaces. Any glove must be replaced when torn, punctured, or when the ability to function as a barrier is compromised. Disposable gloves shall not be reused.

b. Masks, eye protection, and/or face shields will be worn whenever splashes, spray, spatter, or droplets of potentially infectious materials may be generated.

c. Gowns, aprons, and other protective clothing will be worn as dictated by the tasks performed and the degree of exposure anticipated.

d. Surgical caps, head protection, and shoe covers will be worn in instances when gross contamination might reasonably be anticipated.

4. Cleaning, Disinfection, and Decontamination

a. The BSL-1 and BSL-2 laboratories are maintained and cleaned routinely by custodial services. Laboratory personnel are responsible for cleaning and maintenance In BSL-3 suites. Appropriate disinfectants are determined based on the particular agent involved and the type of surfaces to be cleaned or decontaminated. Work surfaces in laboratories will be decontaminated at the beginning and end of each work day and whenever there is an overt spill. Protective coverings on work surfaces (plastic wrap, aluminum foil, or plastic-backed absorbent paper) should be changed regularly and whenever contaminated. Reusable receptacles (bins, pails, cans) will be decontaminated regularly by the laboratory staff. Red-banded cans used for the disposal of special medical waste will be decontaminated immediately upon visible contamination.

b. The safety clearance/work authorization tag system shall be used to assure proper decontamination of equipment and instrumentation before repair. SEPP or other authorized personnel will sign all tags when biological materials, infectious agents, human blood or other potentially infectious materials have been used.

c. Infectious Waste Disposal - Special Medical Waste
A special medical waste program has been developed in coordination with the U.S. Army Garrison which meets all federal and state requirements. BL-3 labs must autoclave or otherwise render non-infectious all waste before it leaves the area. Laboratory waste known to be or potentially contaminated with infectious material is special medical waste and will be decontaminated, autoclaved and/or incinerated. Special medical waste is placed in red-banded receptacles and transported by the Army to the incinerator. Puncture proof needles/sharps disposal containers are used throughout the facility. All sharps containers must be securely closed before removal or disposal. Sealed sharps containers shall be clearly labeled and discarded as medical waste.

Contaminated laundry (uniforms, towels, clothing) when removed in the laboratory, should be placed in appropriate containers and autoclaved before being sent for cleaning. Care will be taken in handling the unautoclaved articles (e.g., holding them away from one's clothing) so as not to cause further contamination.

5. Additional Requirements: HIV/HBV Research Laboratories and Production Facilities

a. This applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. This does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

b. According to 29 CFR 1910.1030(e), all HIV and HBV research laboratories and production facilities shall follow these additional requirements:

i. The work practice controls, personal protective equipment, decontamination procedures and special medical waste handling as described in this policy.

ii. Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

iii. Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before removal from the work area.

iv. Access to the work area shall be limited to authorized persons. Authorized persons shall comply with entry/exit procedures, understand the potential biohazard and meet any specific entry requirements.

v. A biohazard warning sign shall be posted on all access doors whenever work with bloodborne pathogens, OPIM or infected animals are in progress.

vi. All activities involving bloodborne pathogens, and/or OPIM shall be conducted in biological safety cabinets or other physical containment devices within the containment area. No work with these materials shall be conducted on an open bench.

vii. Appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before laundering.

viii. Avoid skin contact with OPIM. Gloves shall be worn when handling infected animals, bloodborne pathogens and OPIM.

ix. Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters that are hydrophobic on the inlet side. Filters shall be checked routinely and replaced as necessary.

x. Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Whenever possible and practicable new safety technology, such as shielded needles, self-sheathing needles, retracting needles or needleless systems, will be utilized. Needles shall not be bent, sheared, resheathed or removed from the syringe following use. The needle/syringe unit shall be placed promptly in an approved sharps container and decontaminated before disposal.

xi. Spills shall be appropriately contained and cleaned up by personnel trained and equipped to work with bloodborne pathogens and OPIM.

xii. A spill or accident resulting in an exposure incident shall be reported immediately to OHS, the laboratory supervisor or the Principal Investigator.

xiii. A biosafety manual shall be prepared or adopted and periodically

reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, required to read instructions on practices and procedures and shall be required to follow them.

xiv. Containment equipment (such as certified biological safety cabinets, respirators, centrifuge safety cups, special protective clothing, and containment caging for animals) shall be used for all activities with bloodborne pathogens and OPIM that pose a threat of exposure to droplets, splashes, spills or aerosols.

xv. Biological safety cabinets shall be certified when installed, whenever they are moved, and at least annually.

c. HIV and HBV research laboratories are required by 29 CFR 1910.1030(e)(3) to follow these additional requirements:

i. Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

ii. An autoclave for decontamination of regulated waste shall be available.

d. HIV and HBV production facilities as outlined in 29 CFR 1910.1030(e)(4), shall also:

i. Work area shall be separated from areas that are open to unrestricted traffic flow within the building with a self-closing, double-door airlock or change room.

ii. Work surfaces, doors, ceilings, floors, and walls shall be water-resistant for easy cleaning. Penetrations in these surfaces shall be easily sealable for easy decontamination.

iii. Each laboratory shall contain a facility for hand washing and an eye wash facility that is readily available within the work area. The sink shall be elbow, foot or automatically operated and shall be located near the door of the work area.

iv. An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

v. A ducted air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through

the entry area. Exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. Proper directional airflow shall be verified.

vi. Access doors to the work area shall be self-closing.

c. Additional Initial Training:

I. Employees working in HIV and HBV research laboratories and production facilities must demonstrate proficiency in standard microbiological practices and safe techniques before working with HIV or HBV. It is the responsibility of the manager, program director, and supervisor to provide training on safe handling techniques and practices. Only after proficiency has been demonstrated may the employee participate in work activities involving infectious agents.

ii. Each employee working in an HIV and HBV research laboratory or production facility must submit to SEPP, through their supervisor, an Additional Initial Training Form to indicate their experience and/or proficiency in handling pathogenic materials. The form can be obtained from SEPP.

6. Communication of Hazards

a. Warning Labels

Warning labels with the fluorescent orange-red biohazard symbol with contrasting lettering or symbols shall be affixed to containers of regulated waste: to refrigerators and freezers which contain human pathogens, human blood or other potentially infectious material; and other containers used to store, transport or ship human pathogens, human blood or other potentially infectious material

i. Required labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

ii. Individual containers of blood or OPIM that are placed in a labeled container for storage, transport, shipment, or disposal are exempt from the labeling requirement.

iii. Regulated waste that has been decontaminated does not need to

be labeled or color-coded.

iii. Red bags or red containers may be substituted for labels.

iv. Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

b. Signs

The biosafety containment level is determined by the biological agent, its concentration, and the laboratory manipulations planned. A biohazard sign with the fluorescent orange-red biohazard symbol indicating the containment level, the responsible investigator, the supervisor, their phone numbers, and the required PPE must be posted at the entrance to work areas.

c. Training and Education

i. All employees with occupational exposure must attend a training program sponsored by SEPP. Training shall be provided at the time of initial assignment and annually thereafter. Documentation of attendance shall be maintained by the SEPP.

ii. Training shall include: information on prevention of exposure, the epidemiology and symptoms of bloodborne diseases; the modes of transmission of bloodborne pathogens; methods for exposure determination; use and limitations of engineering controls; work practices; PPE; information on the types, use, selection, removal, handling, decontamination, and disposal of PPE; appropriate use of biohazard signs; and information on the availability, efficacy, safety, and information on the hepatitis B vaccine.

iii. Training shall also include information on the appropriate action to take and persons to contact in an emergency (e.g., a spill) involving blood or other potentially infectious materials. Emergency first-aid, methods of reporting the incident, and medical follow-ups shall be stressed. Information on post-exposure evaluation and follow-up, which the employer is required to provide, is included.

iv. The employee's supervisor, manager, and/or program director are responsible for reviewing with the employee all specific intra-departmental safety policies and procedures as well as expectations of compliance. This information must be reviewed and updated annually. Individual programs are responsible for

maintaining documentation of this requirement. Additional training must be provided when tasks or procedures are modified or instituted thereby affecting the occupational exposure of the employee.

7. Institutional Biosafety Committee HIV Subcommittee Policy

The following statement addresses the findings of the IBC HIV Subcommittee regarding the Morbidity and Mortality Weekly Report (Vol. 36, No. 2S Supplement, August 21, 1987) “Prevention of HIV Transmission in Health Care Settings”.

Since it is understood that health care workers also wear gloves under conditions where contact with blood or body fluids is anticipated, it is clear that lesions on the hand automatically prevent an individual from handling materials or equipment which contain or may contain infectious virus. The reason for this is to protect even against the low probability occurrence of defective gloves or the inadvertent penetration of the gloves by virus-containing fluids. In contrast to the health care workers, there should be no circumstance in the laboratory where direct contact with infectious material is anticipated. Under BSL-3 conditions, automatic prohibition from working in a BSL-3 laboratory should be limited to lesions of the hands, face, or neck. The judgment on whether a worker with suspect or healing lesions may work (or return to work) is the responsibility of Occupational Health Services. This requires an expert medical opinion and is not a matter for the affected individual or their supervisor to decide independently. The judgment must be made with safety as the overriding factor.

In cases where a decision may not be obvious, e.g., lesions on the arm, leg, or torso, it may be reasonable for certain activities to be permitted while others should be ruled out. By analogy with the penetrated glove situation, the potential for direct contact with virus-containing material should be evaluated. This must involve a discussion between laboratory worker, supervisor, and the Manager, Occupational Health Services.

8. HIV Surveillance Program

a. Introduction

The HIV surveillance program is available to employees of the NCI-Frederick who work with known or suspected live HIV or are potentially

exposed to live HIV in the BSL-3 laboratory. The program is voluntary with no requirement to enroll. It is not a research program, but is intended to be a surveillance program for employee benefit. Refusal to participate in the program will not adversely affect employment status. Refusal to participate will neither preclude participation at a later date nor will it affect an employee's treatment in the event of an occupational exposure. Declining participation does not compromise an employee's benefits under Worker's Compensation where it is demonstrated that an infection has been acquired during the performance of official duties.

b. Eligibility

Eligible participants are identified by the principal investigator who registers all personnel who work with HIV in the laboratory. The registration form is forwarded to Biological Safety for review to determine which employees qualify for the program. In addition, OHS is advised at the time of the initial assignment of an employee to tasks where occupational exposure may take place. The NCI-Frederick Hepatitis B and HIV surveillance eligibility form will be forwarded to OHS by the supervisor upon assignment of personnel. The Manager for Occupational Health Services, who is the HIV surveillance program director, notifies the employee of an appointment in OHS and enrolls the employee in the program. Employees who stop working with live HIV because of a move, change in job description, or a discontinuation of a project will remain in the program for one year following the change.

c. Testing

Samples are taken from participants at periodic intervals and analyzed by ELISA testing for antibodies to HIV. The samples are coded so as to minimize the likelihood of accidental disclosure of any test results.

A unique identifier number is assigned to each program participant for use in reporting laboratory results and confidential record for HIV tests for the OHS surveillance program. A part of the unique identifier includes a portion of the participant's social security number. The disclosure and use of a portion of the participant’s social security number is voluntary. The authority for requesting a portion of the SSN is found in Health General Article Section 18-205, Annotated Code of Maryland and COMAR 10.52.09. The unique identifier information will be used by the testing laboratory for reporting confirmed HIV positive test results to the local or State health department as required by law. An individual may not be denied services for refusal to disclose one’s SSN.

Testing is done by a commercial licensed and approved testing facility

and requires such facility to provide timely testing, confirmatory capability, and timely reporting. In addition to the tube being sent for testing, a second tube is drawn and stored in a serum storage bank for validation testing, if that is necessary. Serum samples collected are sent in a batch to the testing facility. The results of the testing are hand delivered by a courier of the lab in a sealed envelope and given to the program director. Confirmatory tests will be performed on indeterminate and positive results.

Testing is offered semi-annually and at termination of employment. Additional testing at more frequent intervals is offered following an exposure incident.

d. Notification of Results

Participants will be informed of negative laboratory results by mail. Letters will be mailed within four weeks of specimen collection. Notification will be sent to an address indicated by the participant.

Results of the test should be received within four weeks of the venipuncture for any screening test done in this program. Individuals who have not received results within this time frame are instructed to contact OHS, ext. 1096.

The program director will contact individuals with confirmed positive or indeterminate results to inform them of the need for further evaluation and arrange a time for a consultation. In the meeting the program director will personally convey the test results to the program participant. Arrangements will be made for a visit to an infectious disease specialist who interviews and examines the employee, does appropriate testing and reviews the results of the tests. The consultant helps the employee arrange for any further follow-up through a private doctor or appropriate community resources. The consultant, who is not associated with the NCI-Frederick, performs this service under a contractual agreement. information collected by the consultant will not be communicated to OHS or any other person at NCI-Frederick without written permission of the employee. It is solely for the benefit of the employee.

e. Overt Exposure

Quite apart from participation in this program, it is incumbent upon all employees to report immediately any accidents resulting in potential exposure to HIV. Immediate first aid shall be administered at the worksite. Percutaneous injuries are vigorously scrubbed and soaked for 20 minutes with povidone-iodine, 10% solution (e.g. Betadine). Mucous

membranes are irrigated for 15 minutes with normal saline. Consultation regarding chemoprophylaxis will be done on an individual basis.

Following the Public Health Service (PHS) provisional recommendations for chemoprohylaxis after occupational exposure to human immunodeficiency virus (HIV) published on June 7, 1996 (Updated May, 1998), OHS implemented several new procedures to provide timely and appropriate response to an exposure event at the NCI-Frederick, 24 hours per day, 7 days per week.
OHS provides post-exposure prophylaxis (PEP).

A clinical staff member of OHS, NCI-Frederick, provides an assessment and initial administration of post-exposure prophylaxis to exposed NCI-Frederick employees at our facility within 1-2 hours of an HIV exposure event if needed.

Post exposure testing may include blood samples being taken and tested at time zero and at the six week, three, six, and twelve month intervals. If results are negative at twelve months after an accident, the individual may elect to withdraw from the program.

f. Confidentiality

OHS strictly protects the privacy of individuals participating in this program by withholding their names and other identifying information from all persons not directly connected with the conduct of the surveillance program. The linking of the results with the participant's name is done only by the program director. Confidentiality of test results and the names of any persons who test positive will be maintained consistent with the reporting, investigatory, and any legal and contractual obligations on the Operations and Technical Support (OTS) Contractor. Confidentiality of test results obtained as part of accident follow-up likewise will be maintained.

g. Enrollment

Employees who participate in this program understand and agree to the following:

Prior to enrollment in the program, employees will be counseled by OHS to ensure understanding of all provisions of the program including individual responsibilities. The State of Maryland mandates an informed consent form be signed prior to any HIV testing.

In the event of a positive result, a pre-employment sample will be tested and virus isolation attempted if circumstances warrant. The program director will also provide initial counseling in the event of a positive result.

In the event of a positive result, employees will cooperate in any interviews that may be required to identify any risk factors that may be relevant to transmission of HIV, such as life style and laboratory practices.

Accident reporting programs and policies will be followed.

Employees understand that confidentiality of test results and other relevant information will be maintained consistent with the OTS Contractor's reporting, investigatory, and any legal contractual responsibilities.

Employees who are eligible to participate in this program must indicate whether they accept or decline participation.

9. Hepatitis B Vaccination Program

a. Introduction

Infection by hepatitis B virus (HBV) is the most frequent occupational risk among health care workers. The significant factors for nosocomial infection are the intensity of exposure to human blood and the duration of that exposure. The Immunization Practices Advisory Committee of the Public Health Services has recommended that health care workers who have contact with human blood or blood products be vaccinated against HBV. Immunization should take place as early in their careers as possible. In 1992, the OSHA issued rules and regulations about occupational exposure. The standard requires employers to identify employees who may have occupational exposure and to offer them the hepatitis B vaccine within ten working days of their initial assignment.

b. Eligibility

The hepatitis B vaccine is offered without charge by OHS to all NCI-Frederick employees occupationally at risk for acquiring the infection and who lack serologic evidence of pre-existing protective levels of antibody. HBV infection in pregnant women may result in severe disease for the mother and a markedly increased risk of chronic infection for the fetus.

Unvaccinated pregnant women with possible occupational exposure should be strongly encouraged to begin the vaccination series.

Contraindications:

Hypersensitivity to yeast, thimersol (a mercury derivative, added as a preservative in a concentration of 1:20,000) or to the alum adjuvant.

c. Enrollment

Supervisors must identify employees working with human blood or body fluids and other potentially infectious materials and notify OHS. Notification of OHS for employees should occur on the job requisition. OHS will provide a supervisor enrollment form to clarify pathogen registration information. Hepatitis B vaccine will be offered within ten working days of the employee's initial assignment. After explanation of the program by OHS, each enrollee must complete a consent form to receive the vaccine. The form is incorporated into the employee's medical records. If an employee elects not to receive the vaccine, a signed form declining the vaccine is required. If the employee requests the vaccine at a later time, the vaccination series will be provided.

d. Initial vaccination series

The vaccination series consists of three intradeltoid injections. The first dose is administered at the time of enrollment in the program.

For those employees who lack previous serologic evidence of protective levels of antibody, the second and third doses are administered one and six months from the first dose.

e. Serologic monitoring and booster doses

An initial serologic screen for antibodies is performed just prior to the administration of the first dose. If results indicate pre-existing protective levels of antibody, the employee is screened for anti-HBc. The presence of anti-HBc will serve as an indicator of prior infection and no further vaccination will be required. If the employee is anti-HBc negative, OHS may request the employee's permission to check HBs Ag.

All participants will be serologically screened for anti-HBs within 3-6 months of administration of the 3rd dose of vaccine. The need for additional doses of the vaccine and screening for anti-HBs is based upon the six-month anti-HBs S/N value.

10. Accident Reporting, Post Exposure Evaluation and Follow-up

Potential Exposure incident at FCRDC at Ft. Detrick or offsite facilities in Frederick (Government, Charles River and SAIC-Frederick Employees):

Immediately following a potential exposure incident - a cut, splash or other laboratory accident - the employee is to report to OHS. When prudent, laboratory staff should secure the exposed laboratory area.

OHS is on-call 24 hours a day for these incidents. During office hours of Monday through Friday 8:00 AM – 5:00 PM the employee is to report in person at OHS, Building 426, on the NCI-FCRDC Campus, x1096. After hours, the employee must contact Protective Services, x1091 for the on-call OHS health care provider who will meet the employee at OHS. In all cases, the OHS provider will perform an interview and medical evaluation of the person(s) involved and collect the following information: documentation of the route of exposure, the circumstances under which the exposure occurred, identification and documentation of the source individual or material and baseline testing of the source. Postexposure baseline and follow-up of the worker includes collection and testing of blood for HBV, HCV, HTLV, or HIV serological status, as indicated, post-exposure prophylaxis, if indicated, counseling, and evaluation of any reported illnesses. The employee will be provided with a copy of the health care professional's written opinion within 15 days of the initial evaluation. SEPP will investigate the incident to determine whether an exposure actually occurred and prepare a safety evaluation report to indicate the possible need for additional engineering controls, barriers, etc.

Potential exposure of SAIC-Frederick employees at offsite facilities not located in Frederick:

Response to potential exposure incidents that occur at off-site facilities outside of the immediate Frederick Area will be performed by the nearest available medical center. Off-site facilities include those located in Gaithersburg, Shady Grove, Rockville, and nearby areas. Incidents occurring in laboratories located between Bethesda and Frederick should report to Shady Grove Hospital or Suburban Hospital for post exposure assessment and treatment. Telephonic notification is made to OHS at the NCI – FCRDC as soon as possible.

Potential exposure of SAIC-Frederick employees occurring on the NIH campus :

Exposures shall be immediately reported to Occupational Medical Services (OMS) in Building 10. The staff of OMS will make a determination as to disposition. Telephonic notification is made to OHS at the NCI – FCRDC as

soon as possible.

11. Recordkeeping

a. Medical Records

A medical record will be maintained by OHS of all individuals with occupational exposure. The record will include the name and social security number of the employee, and hepatitis B vaccination status. If there has been a documented exposure incident, copies of the accident form, medical evaluation, follow-up procedures, the employer's copy of the healthcare professional's written opinion, and a copy of the information provided to the healthcare professional will be included in the medical records. The medical record will be kept for the duration of employment plus thirty (30) years. The retrovirus exposure surveillance program results are maintained in a separate file in OHS along with the SEPP evaluation.

This information must be kept strictly confidential. No information will be disclosed or reported without the written consent of the employee, except where required by law.

b. Training Records

Records will be maintained for three (3) years from the date of the training. The records will include an outline or summary of the information presented and the dates of the training sessions. Records will also include the names and job of all persons attending the training sessions. Those attending the session will sign an attendance sheet or complete and sign the BBP Professional Study Guide's attached test. The names and qualifications of the trainer(s) will accompany the training records.

c. Sharps Injury Log

If an exposure involving a needlestick occurs, OHS will maintain a sharps injury log. That log will be maintained in a manner that protects the privacy of the employee. The log will contain information regarding the type and brand of device involved in the incident, the location of the incident, and description of the incident.

ATTACHMENT 1

Hepatitis B and HIV Surveillance Eligibility and Addition to Pathogen Registration

NCI-FREDERICK CANCER RESEARCH AND DEVELOPMENT CENTER
HEPATITIS B AND HIV SURVEILLANCE ELIGIBILITY
AND ADDITION TO PATHOGEN REGISTRATION

Employees who may have occupational exposure[1] to human blood or other potentially infectious materials will be added to the hepatitis B surveillance program and offered the hepatitis B vaccine series within ten working days of initial assignment. Employees who work with live HIV will be added to the HIV surveillance program and offered periodic testing. These employees must be added to a current pathogen registration.

An employee is eligible for one or both surveillance programs if the employee meets any of the following criteria:

1) Works directly with the culture, production, concentration, experimentation, or manipulation of live HIV.

2) Works with human blood or other potentially infectious materials (OPIM)[2].

3) Provides direct patient care (medical personnel, physicians, or nurses).

4) Provides first aid as part of regularly assigned duties (Protective Services Officer)

[1]Occupational exposure, according to the Bloodborne Pathogens Standard, means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

[2]OPIM, according to the Bloodborne Pathogen Standard, means "(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood; (2) any unfixed tissue or organ from a human; and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV-or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV."

SUPERVISOR OR DIRECTOR TO COMPLETE (Please type or print legibly.)

Complete form and forward it to Occupational Health Services when an initial assignment is made. It is important to supply all the information requested (A-G). OHS will contact the employee to enroll in the HBV and/or HIV surveillance programs. A copy of the signed form will be returned to you.

A. Name of Employee _____
B. Date to begin assignment _____

C. Laboratory Bldg./Room _____ Phone Ext. _____
D. The above employee is eligible for the one or both surveillance programs because the employee (check all appropriate criterion numbers) 1)_____ 2)_____ 3)_____ 4)_____

E. Principal Investigator _____ Pathogen Reg. #_____

F. Supervisor _____

G. Signature of Supervisor _____ Date _____

FOR OHS AND SEPP ONLY

OHS Staff _____ Date _____

Biosafety Officer _____ Date _____

FORM HIV/HBV ELIG Rev Jun 1997